

APR 29 2004

510(k) Summary

CryoCath Technologies Inc.

SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console

1. SPONSOR

CryoCath Technologies Inc.
16771 Chemin Ste-Marie
Kirkland, Quebec
H9H 5H3, CANADA

Contact Person: Flor del Pilar Arana, Official Correspondent
Telephone: 514-694-1212

Date Prepared: March 12, 2004

2. Device Name

Device Trade Name: SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console
Common/Usual Name: Cryosurgical system
Classification Name: Cryosurgical Unit and Accessories
Device Classification: Class II

3. PREDICATE DEVICES

CryoCath Technologies - SurgiFrost® Cryosurgical System (K021010)

Endocare Inc. - CryoCare Cardiac Surgical System (K011040)

CryoMedical Sciences - AccuProbe 450, Accuprobe 550/530, Accuprobe 600 series (K973190)

Boston Scientific - Cobra Bipolar System (K023288)

Atricure Inc. - Atricure Bipolar Coagulation System (K020919)

Medtronic Inc. - Cardioblate™ Radiofrequency Ablation System (K013392)

4. DEVICE DESCRIPTION

The SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console are intended for minimally invasive cardiac surgical

procedures, including the treatment of cardiac arrhythmias. The SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console freezes the target tissue and blocks the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

The Intended Use does not change as a result of this special 510(k) submission.

The SurgiFrost® 10 cm Cryosurgical Device used with or without the FrostByte™ Clamp, Cryosurgical Console and accessories act together as a System. The system is composed of the following components:

- Cryosurgical Control Panel and Power Cord
- Cryosurgical Console
- Tank Carrier
- Gas Tank Regulator and Wrench
- Gas Hose
- SurgiFrost® Cryosurgical Device (Single Use)
- FrostByte™ Clamp (Single Use)
- Footswitch (optional)

The SurgiFrost® Cryosurgical System consists of a compact, easy-to-operate Cryosurgical Console and associated accessories that include SurgiFrost® 10 cm Cryosurgical Probe to deliver cold temperatures to the targeted tissue. The control console operates off standard 120/230 VAC (60/50 Hz) wall power and utilizes inert argon gas. The Cryosurgical Console controls a single-use, disposable SurgiFrost® Cryosurgical Probe.

5. INTENDED USE

The SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console are intended for minimally invasive treatment of cardiac arrhythmias. The CryoCath SurgiFrost® System freezes the target tissue and blocks the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console is substantially equivalent to the predicate devices based on intended use, design, materials, technological, and operational

characteristics. The differences between the CryoCath devices are minor and raise no new issues of safety or effectiveness.

7. PERFORMANCE TESTING

Information submitted in this premarket notification for the SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console is substantially equivalent to the predicate devices listed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 2004

CryoCath Technologies, Inc.
c/o Ms. Flor del Pilar Arana
Director Regulatory Affairs
16771 Chemin Ste-Marie
Kirkland, Quebec
H9H 5H3, CANADA

Re: K040690

Trade Name: SurgiFrost® 10 cm Cryosurgical Device plus Frostbyte™ Clamp and
Cryosurgical Console

Regulation Number: 21 CFR 878.4350

Regulation Name: Cryosurgical Unit and Accessories

Regulatory Class: II (two)

Product Code: GEH

Dated: April 14, 2004

Received: April 20, 2004

Dear Ms. Pilar Arana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

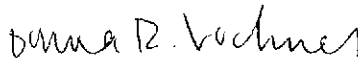
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040690

Device Name: SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console

Indications For Use: The SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The SurgiFrost® 10 cm Cryosurgical Device plus FrostByte™ Clamp and Cryosurgical Console freezes the target tissue and blocks the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

Prescription Use X

AND/OR

Over-The-Counter Use
(21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Kochner
Division Sign-Off
Division of Cardiovascular Devices

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